

5,879,289). Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook (U.S. Patent No. 6,190,310). Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarush et al., with or without Monroe et al. (U.S. Patent No. 5,662,586). Claims 5-10, 12, 17-22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yablonski et al., in view of Luning et al. (U.S. Patent No. 3,390,931). Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chisum et al., in view of Luning et al.

In response, the applicants have amended the claims to more clearly define in the invention and further distinguish over the prior art. A reconsideration of the Examiner's rejections is hereby respectfully requested in view of the following remarks.

The present invention is a hand-held retinal eye viewing device having features which allow it to be readily positioned and maintained in an operative position relative to a patient's eye. It includes an eye cup at the patient end for establishing a desired axial standoff position with respect to a reference eye orbit area defined by the eyebrow and the upper cheekbone of the patient. The eye cup is deformable so as to alert a physician that the device is approaching an operative axial standoff position, and to allow the instrument to be selectively moved to different angular orientations while maintaining the desired radial displacement distance between a patient's pupil center and the imaging axis of the device.

The Cook reference describes an otoscope having a conical shaped disposable tip that is removably connected to the body. It is designed to be used with a receptacle and a specially designed interface between said receptacle and said tip. Generally the axial placement of the tip relative to the ear of a patient is not critical and will vary from use to use.

Yablonski shows an opthalmodynamometer having a speculum that is designed to fit under the eyelids and rest against the sclera. Its primary use is to ascertain the toroid member pressure so that retinal artery blood pressure may be determined. This is not a hand-held device and its structure, and manner and purpose of use are substantially different from the applicants' invention. For example, the speculum in Yablonski is installed under the eyelid, while the eye cup of the present invention is pressed by the user against the eyebrow/upper cheekbone area of the patient.

The Chisum et al. reference shows another opthalmodynamometer device that is, again, similar to the Yablonski device and substantially different from that of the applicants.

The Volk reference shows an image-forming optical system designed to position an image-forming lens a predetermined distance from an examined eye such that the location and size of a formed image may be calculated and measured and measurements obtained. It includes a housing 14 which is positioned with respect to the eye by way of a contact lens 16. A housing 20 is then adjustably disposed within the housing 14, and may be axially and angularly moved within the housing 14 to obtain the desired position. In contrast, the present eye cup does not contact the eye of the patient and is used to properly locate eye illumination as well as eye imaging.

The Yarush reference shows a hand-held endoscopic camera that is intended for a wide variety of use, including the examination of an eye. Generally, the axial positioning of this device is not critical and the operator is likely to vary its position substantially. Although, in one embodiment, an eye speculum 250 (Figure 12B), is provided, it is intended for the purpose of viewing the interior position of the eye (e.g. lens and eyelids) rather than establishing an axial position for illumination of the retina as in the present invention. Accordingly, its shape and the manner in which it engages the patient is substantially different from those of the applicants.

The Monroe et al. reference shows a hand-held diagnostic instrument which can be easily configured for different purposes by installing a different front cover and back cover. However, there is no provision or structure for engaging the patient and conducting an examination of the eye as intended and provided for in the present invention.

The Luning et al. reference shows a telescopic eye piece assembly for minimizing face illumination by phosphor screen glow in night vision sighting devices. It includes an accordion fold tubular member which is adapted to act upon a shutter so as to automatically open the shutter when the eye piece has been acted on by the compression force of the user's eye. The eye piece is therefore provided for the purpose of preventing the phosphor screen glow from projecting outwardly from the eye area where it can be seen by an enemy. The applicants submit that the purpose and structure is therefore substantially different from applicants eye piece and would not be readily or obviously adaptable to the applicants use and structure, wherein the eye piece is applied to the person being observed rather than to the person observing.

Referring now to the claims as amended, independent claims 1, 13 and 25 recite an apparatus or method which includes an eye viewing device having an eye cup disposed at a patient end thereof, with the eye cup being sized to substantially correspond to an eye orbit which is generally defined by an eyebrow and an upper portion of a cheekbone. Support

for the added language is the claims can be found in Figure 1A and on page 8, lines 13 and after of the specification. For the reasons discussed hereinabove, none of the references shows or suggests such a structure and would rather tend to lead one away from such claimed structure.

Claims 5, 6, 17, 18 and 26 recite further features relating to a deformable bellows. None of the references taken individually or in combination show such a structure. Although a deformable bellows is shown in a night viewing device, for the reasons discussed hereinabove, it would not be obvious to one skilled in the art to adapt that feature to those devices shown in the other references to obtain the applicants invention.

Claims 7-10, 19-22 and 28 recite a further feature of the eye viewing device wherein the eye cup is adapted to pivot substantially about the pupil of the patient eye cup. None of the references taken individually or in combination shows or suggests such a feature.


For the reasons discussed hereinabove, the applicants believe that the claims, as amended, are patentable distinctive over the cited references. A reconsideration of the Examiners rejections and a passing of the case to issue is therefore respectfully requested.

If the Examiner believes that contact with Applicant's attorney would be advantageous toward the disposition of this case, the Examiner is herein requested to call Applicant's attorney at the phone number noted below.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0289.

Respectfully submitted,

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PATENT TRADEMARK OFFICE

**Attachment A**

Paragraph beginning at line 15, page 3 has been amended as follows:

An eye viewing device according to the invention includes an eye cup having patient end adapted to be received at an eye orbit of a patient, the eye orbit being generally defined by an eyebrow and upper cheekbone of a patient. In one aspect of the invention, the outer diameter of the patient end of the eye cup is sized to correspond to a patient's eye orbit. Because a center of a patient eye is located substantially at the center of an eye orbit, the sizing of the patient end outer diameter corresponding to an eye orbit operates to aid in the radial displacement positioning of the device.

Paragraph beginning at line 3, page 10 has been amended as follows:

Axial standoff positioning between an eye viewing device 10 and an eye must be substantially precise in retinal viewing devices having conical illumination as can be seen by comparison of Figs. 3A and 3B. Conical illumination systems generate a cone of light having light rays that converge at an apex and diverge thereafter. Fig. 3A shows a cone of light illumination in which apex, ax, of the cone of light 34 is spaced apart from a pupil 32 while Fig. 3B shows a cone of light illumination in which apex, ax, of cone of light 34 is positioned at a pupil 32. Comparing to Figs. 3A and 3B it can be seen that illumination of a retina illuminated by a conical illumination system improves when apex, ax, of the conical illumination is substantially positioned at a pupil. In the specific embodiment of the deformable configured eye cup shown in Figs. 1A-3G, apex, ax, of cone of light 34 is at a position forward of pupil 32, indicated in Fig. 3A when eye cup 20 first contacts an eye orbit 25, and at a position substantially within pupil 32 when eye cup 20 is in an operative deformed configuration. Examples of retinal viewing ophthalmoscopes having conical illumination systems are described in commonly assigned U.S. Patent No. 6,065,837, [Application Serial No. 09/198,545,] and concurrently filed Application Serial No. 09/444,161 entitled "Eye Viewing Device for Retinal Viewing through Undilated Pupil," both of which are incorporated herein by reference.

Paragraph beginning at line 12, page 12 has been amended as follows:

The bellows-configured eye cup described with reference to Figs. 2A-2G can be made to pivot at a pivot point proximate a pupil 32 by configuring eye cup 20 to have proportionately thinner material at the bellows sections toward patient end 22 of eye cup 20. As seen in the cross-sectional view of Fig. 2E, the walls of eye cup 20 are formed

gradually thinner toward patient end 22 to produce pivoting toward patient end 22. First bellows section 41 has a smaller thickness than second bellows section 42 which has a smaller thickness than third bellows section 43. The walls 47 of the third bellows [47] 43 are substantially thicker than the walls 45 and 46 of the first and second bellows [45] 41, and [46] 42, respectively. The configuration shown in Fig. 2[e]E provides an eye cup which pivots substantially toward patient end 22 when eye cup 20 is in an axially deformed or compressed configuration and the device is moved angularly.

Paragraph beginning at line 11, page 13 has been amended as follows:

Further, referring to Fig. 1[a]A showing a device according to the invention in use, it can be seen that eye cup 20 allows device 10 to be stabilized against a patient's eye orbit during eye viewing. Accordingly, in addition to aiding the task of positioning device 10 in an operative position, eye cup 20 eases the task of maintaining an operative position once an operative position has been achieved.

Paragraph beginning at line 16, page 13 has been amended as follows:

Additional specific structural details of a preferred embodiment of eye cup 20 are described with reference again to Figs. 2A-2[H]G. Bottom surface 26 of cup 20, which is the patient contact surface, preferably defines a flange configuration as is best seen by bottom view Fig. 2C. The flange-shaped bottom surface enhances patient comfort and, by providing for substantial contact of cup 20 with eye orbit 25, encourages radial stabilization of eye cup 20 on eye orbit 25. While bottom surface 26 is substantially circular, it is contemplated that the bottom surface 26 can be configured in other configurations, including configurations that more precisely approximate the actual shape of a patient's eye orbit.

Paragraph beginning at line 5, page 14 has been amended as follows:

While eye cup outer diameter OD is sized to correspond to an eye orbit as explained previously, inner diameter ID of cup 20 is sized so as not to substantially interfere with a patient's eyelashes during blinking or to interfere with the illumination and imaging performance of the eye viewing device. Eye cup 20 can have an outer diameter of between about 35mm and 55mm and an inner diameter of between about 20mm and about

40mm. In the embodiment of Figs. 2A-2[H]G eye cup 20 has an outer diameter of about 45mm and an inner diameter of about 32mm at bottom surface 26.

**Attachment B**

Please replace the paragraph on page 3, line 15 with the following paragraph:

B1  
An eye viewing device according to the invention includes an eye cup having patient end adapted to be received at an eye orbit of a patient, the eye orbit being generally defined by an eyebrow and upper cheekbone of a patient. In one aspect of the invention, the outer diameter of the patient end of the eye cup is sized to correspond to a patient's eye orbit. Because a center of a patient eye is located substantially at the center of an eye orbit, the sizing of the patient end outer diameter corresponding to an eye orbit operates to aid in the radial displacement positioning of the device.

Please replace the paragraph on page 10, line 3 with the following paragraph:

B2  
Axial standoff positioning between an eye viewing device 10 and an eye must be substantially precise in retinal viewing devices having conical illumination as can be seen by comparison of Figs. 3A and 3B. Conical illumination systems generate a cone of light having light rays that converge at an apex and diverge thereafter. Fig. 3A shows a cone of light illumination in which apex, ax, of the cone of light 34 is spaced apart from a pupil 32 while Fig. 3B shows a cone of light illumination in which apex, ax, of cone of light 34 is positioned at a pupil 32. Comparing to Figs. 3A and 3B it can be seen that illumination of a retina illuminated by a conical illumination system improves when apex, ax, of the conical illumination is substantially positioned at a pupil. In the specific embodiment of the deformable configured eye cup shown in Figs. 1A-3G, apex, ax, of cone of light 34 is at a position forward of pupil 32, indicated in Fig. 3A when eye cup 20 first contacts an eye orbit 25, and at a position substantially within pupil 32 when eye cup 20 is in an operative deformed configuration. Examples of retinal viewing ophthalmoscopes having conical illumination systems are described in commonly assigned U.S. Patent No. 6,065,837, and concurrently filed Application Serial No. 09/444,161 entitled "Eye Viewing Device for Retinal Viewing through Undilated Pupil," both of which are incorporated herein by reference.

Please replace the paragraph on page 12, line 12 with the following paragraph:

B3  
The bellows-configured eye cup described with reference to Figs. 2A-2G can be made to pivot at a pivot point proximate a pupil 32 by configuring eye cup 20 to have proportionately thinner material at the bellows sections toward patient end 22 of eye cup 20. As seen in the cross-sectional view of Fig. 2E, the walls of eye cup 20 are formed

gradually thinner toward patient end 22 to produce pivoting toward patient end 22. First bellows section 41 has a smaller thickness than second bellows section 42 which has a smaller thickness than third bellows section 43. The walls 47 of the third bellows 43 are substantially thicker than the walls 45 and 46 of the first and second bellows 41, and 42, respectively. The configuration shown in Fig. 2E provides an eye cup which pivots substantially toward patient end 22 when eye cup 20 is in an axially deformed or compressed configuration and the device is moved angularly.

Please replace the paragraph on page 13, line 9 with the following paragraph:

Further, referring to Fig. 1A showing a device according to the invention in use, it can be seen that eye cup 20 allows device 10 to be stabilized against a patient's eye orbit during eye viewing. Accordingly, in addition to aiding the task of positioning device 10 in an operative position, eye cup 20 eases the task of maintaining an operative position once an operative position has been achieved.

Please replace the paragraph on page 13, line 16 with the following paragraph:

Additional specific structural details of a preferred embodiment of eye cup 20 are described with reference again to Figs. 2A-2G. Bottom surface 26 of cup 20, which is the patient contact surface, preferably defines a flange configuration as is best seen by bottom view Fig. 2C. The flange-shaped bottom surface enhances patient comfort and, by providing for substantial contact of cup 20 with eye orbit 25, encourages radial stabilization of eye cup 20 on eye orbit 25. While bottom surface 26 is substantially circular, it is contemplated that the bottom surface 26 can be configured in other configurations, including configurations that more precisely approximate the actual shape of a patient's eye orbit.

Please replace the paragraph on page 14, line 5 with the following paragraph:

While eye cup outer diameter OD is sized to correspond to an eye orbit as explained previously, inner diameter ID of cup 20 is sized so as not to substantially interfere with a patient's eyelashes during blinking or to interfere with the illumination and imaging performance of the eye viewing device. Eye cup 20 can have an outer diameter of between about 35mm and 55mm and an inner diameter of between about 20mm and about



cont'd  
B6

40mm. In the embodiment of Figs. 2A-2G eye cup 20 has an outer diameter of about 45mm and an inner diameter of about 32mm at bottom surface 26.

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**Attachment C**

Please cancel claims 2, 14 and 34, without prejudice.

1. (Amended) An eye viewing device comprising:  
a housing having a patient end and an observer end; and  
an eye cup disposed at said patient end[.], said eye cup having a patient end being sized such that its outer edge substantially corresponds to an eye orbit of a patient, wherein said eye orbit is generally defined by an eyebrow and an upper portion of a cheekbone of said patient.
3. (Amended) The eye viewing device of claim 1, wherein [a] said patient end of said eye cup comprises a flange configured bottom surface sized to substantially correspond to [an] said eye orbit of a patient.
4. (Amended) The eye viewing device of claim 1, wherein [a] said patient end of said eye cup comprises a flange configured bottom surface sized to substantially correspond to [an] said eye orbit of a patient, and [is] its interior is sized to accommodate a patient's eyelashes.
5. (Amended) The eye viewing device of claim 1, wherein said eye cup is deformable so that contact of said eye cup with an [aye] eye orbit alerts [said] an observer that said device is approaching an operative position.
11. (Amended) The eye viewing device of claim 1, wherein said eye cup is detachably attachable to said [eye viewing device] housing.
13. (Amended) An apparatus for aiding in the positioning of an eye viewing device relative to a patient, said apparatus comprising:  
a device end adapted to be attached to a patient end of said eye viewing device; and  
a patient end adapted to be received at an eye orbit of said patient[.], wherein said patient end of said apparatus is sized such that its outer edge corresponds to an eye orbit of a patient, said eye orbit being generally defined by an eyebrow and an upper portion of a cheekbone of said patient.

15. (Amended) The apparatus of claim 13, wherein a patient end of said apparatus comprises a flange configured bottom surface sized to substantially correspond to [an] said eye orbit of a patient.

16. (Amended) The apparatus of claim 13, wherein [a] said patient end of said apparatus comprises a flange configured bottom surface sized to substantially correspond to [an] said eye orbit of a patient, and [in] an interior is sized to accommodate a patient's eyelashes.

17. (Amended) The apparatus of claim 13, wherein said apparatus is deformable so that contact of said apparatus with [an] said eye orbit alerts an operator that said device is approaching an operative position.

19. (Amended) The apparatus of claim 13, wherein said apparatus [includes an axis, and is] adapted to pivot substantially about said patient end of said apparatus.

23. (Amended) The apparatus of claim 13, wherein said apparatus is detachably attachable to [an] said eye viewing device.

25. (Amended) A method for positioning an eye viewing device in an operative position relative to a patient, said eye viewing device having a patient end, said method comprising the steps of:

providing a spacer on said patient end of said eye viewing device; and  
moving said device toward said patient at least until said spacer contacts said patient[.] at the eyebrow and upper cheekbone area.

29. (Amended) A [medical] retinal viewing device comprising:  
a housing having an operator end and a patient end;  
an attachment interface formed at said patient end adapted to detachably receive an attachment; [and]

[an] said attachment consisting of a lens assembly and an optical filter assembly.  
[disposed in said attachment interface.]

32. (Amended) The device of claim 29, wherein said [attachment comprises an otoscope] lens assembly comprises an outer ear viewing assembly.

33. (Amended) The device of claim 29, wherein said [attachment comprises an episcope] lens assembly comprises a skin viewing assembly.

34. (Amended) The device of claim 29, wherein said [attachment comprises a corneal viewing lens assembly] lens assembly comprises a corneal viewing assembly.

35. (Amended) The device of claim 29, wherein said [attachment comprises a magnifier lens assembly] lens assembly comprises a magnifier assembly.

**Attachment D**

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1. (Amended) An eye viewing device comprising:  
a housing having a patient end and an observer end; and  
an eye cup disposed at said patient end, said eye cup having a patient end being sized such that its outer edge substantially corresponds to an eye orbit of a patient, wherein said eye orbit is generally defined by an eyebrow and an upper portion of a cheekbone of said patient.

3. (Amended) The eye viewing device of claim 1, wherein said patient end of said eye cup comprises a flange configured bottom surface sized to substantially correspond to said eye orbit of a patient.

4. (Amended) The eye viewing device of claim 1, wherein said patient end of said eye cup comprises a flange configured bottom surface sized to substantially correspond to said eye orbit of a patient, and its interior is sized to accommodate a patient's eyelashes.

5. (Amended) The eye viewing device of claim 1, wherein said eye cup is deformable so that contact of said eye cup with an eye orbit alerts an observer that said device is approaching an operative position.

B8

11. (Amended) The eye viewing device of claim 1, wherein said eye cup is detachably attachable to said housing.

B9

13. (Amended) An apparatus for aiding in the positioning of an eye viewing device relative to a patient, said apparatus comprising:  
a device end adapted to be attached to a patient end of said eye viewing device; and  
a patient end adapted to be received at an eye orbit of said patient, wherein said patient end of said apparatus is sized such that its outer edge corresponds to an eye orbit of a patient, said eye orbit being generally defined by an eyebrow and an upper portion of a cheekbone of said patient.

15. (Amended) The apparatus of claim 13, wherein a patient end of said apparatus comprises a flange configured bottom surface sized to substantially correspond to said eye orbit of a patient.

16. (Amended) The apparatus of claim 13, wherein said patient end of said apparatus comprises a flange configured bottom surface sized to substantially correspond to said eye orbit of a patient, and an interior is sized to accommodate a patient's eyelashes.

17. (Amended) The apparatus of claim 13, wherein said apparatus is deformable so that contact of said apparatus with said eye orbit alerts an operator that said device is approaching an operative position.

19. (Amended) The apparatus of claim 13, wherein said apparatus adapted to pivot substantially about said patient end of said apparatus.

23. (Amended) The apparatus of claim 13, wherein said apparatus is detachably attachable to said eye viewing device.

25. (Amended) A method for positioning an eye viewing device in an operative position relative to a patient, said eye viewing device having a patient end, said method comprising the steps of:  
providing a spacer on said patient end of said eye viewing device; and  
moving said device toward said patient at least until said spacer contacts said patient at the eyebrow and upper cheekbone area.

29. (Amended) A retinal viewing device comprising:  
a housing having an operator end and a patient end;  
an attachment interface formed at said patient end adapted to detachably receive an attachment;  
said attachment consisting of a lens assembly and an optical filter assembly.

32. (Amended) The device of claim 29, wherein said lens assembly comprises an outer ear viewing assembly.

33. (Amended) The device of claim 29, wherein said lens assembly comprises a skin viewing assembly.

34. (Amended) The device of claim 29, wherein said lens assembly comprises a corneal viewing assembly.

35. (Amended) The device of claim 29, wherein said lens assembly comprises a magnifier assembly.

Amended  
B14

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